

**THE COMMONWEALTH OF MASSACHUSETTS***Office of the Secretary of the Commonwealth***Regulation Filing** *To be completed by filing agency***CHAPTER NUMBER:** 105 CMR 533.000**CHAPTER TITLE:** Fish and Fishery Products**AGENCY:** Department of Public Health**SUMMARY OF REGULATION**

State the general requirements and purposes of this regulation: These amendments promote consistency with federal standards, rules and regulations and establish minimum standards for those persons engaged in the retail sale and wholesale manufacturing and/or distribution of seafood and to insure the safe and sanitary handling, processing and distribution of seafood. The amended 105 CMR 533.000 will incorporate by reference, the federal Food and Drug Administration's regulation 21 CFR part 110: Current Good Manufacturing Practice in Manufacturing, Packing or Holding of Human Food and Part 123: Fish and Fishery Products as well as relevant sections of the NSSP's Model Ordinance.

REGULATORY AUTHORITY: MGL c.94, ss 88C, 192, 305A; MGL c.111, ss 3 and 5; MGL c. 130, s.80**AGENCY CONTACT:** Paul Tierney **PHONE:** 617-983-6760**ADDRESS:** 305 South Street, Jamaica Plain, MA. 02133**Compliance with M.G.L. c.30A****EMERGENCY ADOPTION**

If this regulation is adopted as an emergency regulation, state the nature of the emergency.

N/A

PRIOR NOTIFICATION AND/OR APPROVAL

If prior notification to and/or approval of the Governor, legislature or others was required, list each notification, approval and date, including notice to the Local Government Advisory Commission:

MMA 3/26/01

EOCD 3/26/01

PUBLIC REVIEW

Was notice of the hearing or comment period filed with the Secretary of State published in appropriate newspapers and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period?

Yes ☒ Date of public hearing or comment period: May 1,2 & 3, 2001

FISCAL EFFECT

Estimate the fiscal effect on the public and private sectors:

For the first and second years:

For the first five years:

No fiscal effect: X

SMALL BUSINESS IMPACT

State the impact of this regulation on small business. Include a description of reporting, record keeping and other compliance requirements as well as the appropriateness of performance versus design standards and whether this regulation duplicates or conflicts with any other regulation. If the purpose of this regulation is to set rates for the state this section does not apply.

No additional reporting or recordkeeping requirements; no performance or design standards are relevant; no duplication or conflict with any other regulation.

CODE OF MASSACHUSETTS REGULATIONS INDEX

List key subjects entries that are relevant to this regulation:

105 CMR 533.000

PROMULGATION

State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) to replace or amend. List by CMR number:

Amends 105 CMR 533.000

ATTESTATION

The regulation described herein and attached hereto is a true copy of the regulation adopted

by this agency. ATTEST:

Signature: *Ann Miller* Date: October 9, 2001

Publication *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: 933 DATE: 10/26/01

EFFECTIVE DATE: 10/26/01

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:
CMR: Vol.

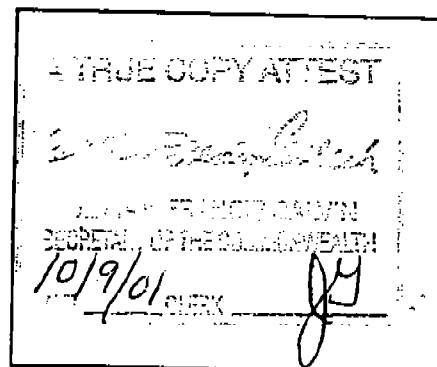
83,84

3345 - 3362

Insert these pages:

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3345 - 3362.2



105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 533.000: FISH AND FISHERY PRODUCTS

Section

- 533.001: Purpose
- 533.002: Authority
- 533.003: Adoption of Federal Regulation 21 CFR Part 110.00: Current Good Manufacturing Practices in Manufacturing, Packing or Holding Human Food
- 533.004: Adoption of Federal Regulation 21 CFR Part 123.00: Fish and Fishery Products
- 533.005: Adoption of the National Shellfish Sanitation Program Model Ordinance
- 533.006: Definitions
- 533.007: Supplemental Fish and Fishery Products Regulations
- 533.008: Market Standard for Shellfish Sold in Massachusetts
- 533.010: General Administration
- 533.011: Obtaining a Permit
- 533.012: Seafood Operation Operating Without a Permit
- 533.013: Inspections
- 533.014: Notice of Violations/Order to Correct
- 533.015: Plan of Correction
- 533.016: Procedures when Infection is Suspected
- 533.017: Enforcement
- 533.020: Severability
- 533.030: Variance

533.001: Purpose

The purpose of 105 CMR 533.000 is to promote consistency with federal standards, rules, and regulations and to establish minimum standards for those persons engaged in the retail sale and wholesale manufacture and/or distribution of seafood and to insure the safe and sanitary handling, processing, and distribution of seafood products.

533.002: Authority

105 CMR 533.000 is promulgated pursuant to M.G.L. c. 94, §§ 88C, 192, and 305A, M.G.L. c. 111, §§ 3 and 5 and M.G.L. c. 130, § 80.

533.003: Adoption of Federal Regulation 21 CFR Part 110.00: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food

The Department hereby adopts and incorporates by reference the federal regulation 21 CFR Part 110.00: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food published by the Office of the Federal Register, National Archives and Records Administration dated April 1, 1999, to the extent the provisions are not inconsistent with specific provisions of 105 CMR 533.000.

533.004: Adoption of Federal Regulation 21 CFR Part 123.00: Fish and Fishery Products

The Department hereby adopts and incorporates by reference the following sections of federal regulation 21 CFR Part 123.00: Fish and Fishery Products published by the Office of the Federal Register, National Archives and Records Administration dated April 1, 1999, to the extent the provisions are not inconsistent with specific provisions of 105 CMR 533.000: Subpart A – General Provisions, excluding § 123.6(g), Subpart B – Smoked & Smoke-flavored Fishery Products, and Subpart C – Raw Molluscan Shellfish.

533.005: Adoption of National Shellfish Sanitation Program Model Ordinance

The Department hereby adopts and incorporates by reference the following sections of the 1999 Revised National Shellfish Sanitation Program (NSSP) Model Ordinance (MO) published by the United States Department of Health and Human Services, to the extent the provisions are not inconsistent with specific provisions of 105 CMR 533.000: Definitions, Chapters I, II @ .01 and @ .02(A) and (C), VI, VIII .02(D) and (E) and .03, and IX through XV.

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Copies of the 1999 Model Ordinance are available on-line:

1999 Model Ordinance in a PDF version is available on-line and can be downloaded from the following website: http://www.issc.org/On-Line_docs/onlinedocs.htm

533.006: Definitions

For the purposes of 105 CMR 533.000, the following terms shall have the meanings hereinafter specified. These definitions shall be in addition to those contained within the federal regulations 21 CFR Part 110, 21 CFR Part 123 and the National Shellfish Sanitation Program Model Ordinance.

Adequate or Approved Water Source and Potable Water are used interchangeably to mean the source of water used in the seafood operation, anywhere in the facility, shall be from:

- (1) a source meeting the quality standards of 310 CMR 22.00: *Drinking Water*, promulgated by the Department of Environmental Protection (DEP);
- (2) manufactured brine that meets the drinking water standards but has an elevated salt content; and/or
- (3) water only deemed appropriate for use in live animal storage, i.e. lobster pounds, wet storage, etc.

Adulterated means the definition in M.G.L. c. 94, § 186.

Bait means any fish or fishery product, used for the attraction and harvest of seafood, which is not of sufficient sanitary quality for human consumption.

Certified Dealer means a wholesale dealer approved by the Department for the interstate shipment of molluscan shellfish.

Commissioner means the Commissioner of the Department of Public Health.

Critical Violation or Critical Deficiency means any violation of 105 CMR 533.000 by a facility or any other occurrence or condition in a facility that has the potential to pose a danger to public health and shall include, but not be limited to, the following:

- (1) seafood from an unapproved or unknown source or seafood that is or may be adulterated, misbranded, or otherwise unfit for human consumption;
- (2) any activity that misrepresents the origination and/or disposition of any seafood intended for human consumption;
- (3) potentially hazardous seafood that is held longer than four hours for preparation or service at a temperature which is greater than 45°F (7.2°C) (in the case of cold seafood) or less than 140°F (60°C) (in the case of hot seafood);
- (4) inadequate equipment to maintain product temperature;
- (5) a person infected with a communicable disease, which can be transmitted through seafood, working as a seafood handler in a seafood operation;
- (6) sewage or liquid waste that is not disposed of in an approved and sanitary manner, or that contaminates or may contaminate any seafood, areas used to store or prepare seafood, or any areas frequented by customers or employees;
- (7) toilets and facilities for washing hands are not provided;
- (8) the supply of water is from an unapproved source or there is insufficient pressure and the seafood operation does not use single service articles and bottled water from an approved source;
- (9) a defect exists in the system supplying potable water that may result in the contamination of the water;
- (10) insects, rodents or other animals are present in the facility;
- (11) toxic items are improperly labeled, stored or used;
- (12) severe unsanitary conditions that threaten to contaminate the facility, a part of the facility or a particular product.
- (13) conducting activities not approved or endorsed by the Division; or
- (14) power outage.

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The failure to include other violations, occurrences, or conditions in 105 CMR 533.006: Critical Violation or Critical Deficiency shall not be construed as a determination that such other violations, occurrences, or conditions are not, or may not be considered a critical violation.

Department means the Massachusetts Department of Public Health.

Division means the Division of Food and Drugs of the Massachusetts Department of Public Health.

Division of Marine Fisheries means the Division of Marine Fisheries of the Massachusetts Department of Fisheries, Wildlife, and Environmental Law Enforcement.

Embargo means the definition in M.G.L. c. 94, § 189A.

Facility *see* Plant.

Frozen means the product temperature has reached 0°F (-18°C) or lower at the thermal center, after thermal stabilization.

Imminent Danger to the Public Health means that a condition or a combination of conditions exist that, in the opinion of the Department, would place the public at risk for a foodborne related illness or other similar hazard, if not immediately corrected.

Inspector means an agent of the Commissioner of the Massachusetts Department of Public Health as defined in M.G.L. c. 111, § 9.

Landing means that point in time when seafood has been brought on-shore after harvesting.

Master Digger means an individual holding a permit for the digging or taking of shellfish from an area determined under M.G.L. c. 130, § 74 to be contaminated.

Misbranded means the definition in M.G.L. c. 94, § 187.

Noncompliance, Failure to Comply and Violation each mean any act or failure to act, which constitutes, or results in, one or more of the following:

- (1) Engaging in any seafood operation, subject to regulation by 105 CMR 533.000 or applicable statute, without a permit whenever engaging in such an operation requires a permit.
- (2) Engaging in any activity prohibited by, or not in compliance with, 105 CMR 533.000, or any order or permit issued or adopted by the Department pursuant to 105 CMR 533.000 or applicable statute.
- (3) Failing to do, or failing to do in a timely manner, anything required by 105 CMR 533.000, or any order or permit issued or adopted by the Department pursuant to 105 CMR 533.000 or applicable statute.

Permit means any permit required by law or by regulation or order of the Department.

Permit Number means the number assigned to a permit holder by the Division of Marine Fisheries.

Person means any individual, partnership, corporation, association, or other legal entity.

Plant or Facility means the building or parts thereof, used for or in connection with a seafood operation. For the purposes of 105 CMR 533.000, plant or facility may be used in connection with a wholesale seafood operation or a retail food establishment.

Potentially Hazardous Food means any food or ingredient, natural or synthetic, in a form capable of supporting:

- (1) the rapid and progressive growth of infectious or toxigenic microorganisms or
- (2) the slower growth of *C. botulism*.

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(3) Excluded are the following:

- (a) foods with a water activity (a_w) value of 0.85 or less;
- (b) foods with a hydrogen concentration (pH) level of 4.6 or below;
- (c) foods in unopened hermetically sealed containers, which have been commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution; and
- (d) foods for which laboratory evidence (acceptable to the Department) demonstrates that rapid and progressive growth of infectious and toxigenic microorganisms or the slower growth of *C. botulism* cannot occur.

Refrigeration means the management of the environmental temperature by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the product to, and will maintain it at 45°F (10°C) or less.

Reduced Oxygen Packaging means the removal or partial removal of oxygen from a package, with or without replacing it with a gas mixture, to control food spoilage. Reduced Oxygen Packaging (ROP) includes controlled atmospheric packaging (CAP), modified atmospheric packaging (MAP), straight vacuum packaging (VP), sous vide and cook-chill.

Retail Seafood Operation means an operation that stores and sells seafood directly to the consumer.

Seafood means all fish and/or fishery products.

Sell means to sell, offer or expose for sale, barter, trade, deliver, give away, possess with an intent to sell, or dispose of in any other commercial manner.

Shellfish Transaction Card means a card issued by the Division of Marine Fisheries to a permitted shellfish harvester to be used in connection with each sale of shellfish by the harvester to a wholesale dealer.

Transaction Slip means a serialized multi-copy form approved by the Division used by wholesale dealers to record original shellfish purchase transactions by mechanical imprinting from the Shellfish Transaction Card.

Wholesale Seafood Operation means any activity comprising any or all of the following: handling, storing, preparing, heading, eviscerating, shucking, freezing, manufacturing, preserving, packing, labeling, shipping or selling raw fish and/or shellfish, whether frozen or unfrozen, in bulk or for resale not directly to the consumer in a facility approved by the Department.

Wholesale Dealer means a person who is permitted by the Department to conduct a wholesale seafood operation and who may operate one retail store from a single, fixed location.

533.007: Supplemental Fish and Fishery Products Regulations

The following requirements are in addition to those established in 105 CMR 533.003, 533.004, and 533.005:

(A) Additional Hazard Analysis Critical Control Point (HACCP) Requirements. In addition to the record keeping requirements established in 21 CFR 123.00: Fish and Fishery Products and the Model Ordinance, each wholesale dealer shall keep and maintain the following information:

- (1) for those products for which it is determined that no hazard exists, a written justification supporting that finding;
- (2) a written Sanitation Standard Operating Procedure (SSOP);
- (3) a written Corrective Action Plan for deviations of the HACCP plan; and
- (4) a current written contingency plan for use in initiating and accomplishing a product recall in accordance with 21 CFR §§ 7.40 through 7.49, 7.53 and 7.55. The plan shall include procedures for the notification of the Division, consumer notification, and recall of the products.

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(B) Failure to Comply with HACCP Regulations. Failure of a wholesale dealer to comply with the HACCP requirements of 21 CFR 123.6(a) through (f) and 105 CMR 533.007(A), where applicable, may render the fish or fishery product(s) adulterated and/or constitute a violation of 105 CMR 533.000.

(C) Storage and Transportation of Frozen and Refrigerated Seafood.

(1) Any warehouse or transportation terminal building used to store shellfish must comply with the requirements of 21 CFR Part 123, the National Shellfish Sanitation Program Model Ordinance and 105 CMR 533.000.

(2) Delivery and Transportation.

(a) All wholesale dealer's seafood delivery vehicles and wholesale trucks shall be equipped with a combination of insulation and mechanical refrigeration, capable of maintaining a product temperature of 0°F (-18°C) or lower for frozen seafood and 45°F (7.2°C) or lower for refrigerated seafood, while loaded with any frozen or refrigerated seafood.

(b) Frozen and refrigerated seafood delivery trucks shall be equipped with a thermometer or other appropriate means of temperature measurement, indicating air temperature inside the vehicle.

(c) The product temperature for any individual consignment of frozen seafood shall not exceed 0°F (-18°C), or for refrigerated seafood shall not exceed 45°F (7.2°C), during any loading, transportation or unloading of said consignment.

(d) Frozen or refrigerated seafood shall be loaded and unloaded in a manner to insure a minimum of exposure to temperatures above 0°F (-18°C) or 45°F (7.2°C), respectively.

(3) Handling Practices for Over-the-Road Transportation.

(a) Vehicles shall be pre-cooled to temperatures required under 105 CMR 533.007(C)(2)(a) before loading.

(b) Processed frozen and refrigerated seafood shall be securely packaged or wrapped in a sanitary manner before offered for transportation. Other frozen or refrigerated seafood shall be shipped in accordance with good sanitary practices.

(c) Frozen and refrigerated seafood shall be loaded within a vehicle of transportation so as to provide for free circulation of refrigerated air to the front, rear, top, bottom and both sides of the load, except for vehicles of envelope type construction wherein refrigerated air circulates within walls of said vehicles.

(d) The mechanical refrigerating unit of vehicles shall be started, maintained in operation, and doors of vehicles shall be kept closed during any time interval when loading or unloading operations cease or are interrupted.

(e) Any vehicle engaged in the wholesale transportation of seafood products shall have the name of the company and permit number issued by the Division of Marine Fisheries clearly displayed on the two sides of its exterior. At a minimum, the lettering shall be four inches in height and of a color in contrast to the truck exterior.

(4) Vehicles used for the transportation of seafood shall not be used for any other food products without adequate separation and protection to avoid cross-contamination.

(5) Seafood products transported by a harvester or retailer shall be adequately protected from temperature abuse and environmental contamination. A retailer shall use mechanical refrigeration or ice from an approved source to maintain the product at 45°F (7.2°C) or below.

(6) When a wholesale dealer is also a master digger, separate vehicles for each activity shall be required unless the dealer adequately addresses the potential hazards in its HACCP plan and SSOPs.

(7) If a person holding a wholesale dealer or wholesale truck permit leases a vehicle to transport seafood products, the person shall provide the Department with the vehicle identification number and the registration number of the vehicle(s) leased. Any time a vehicle is added, removed or exchanged, the dealer shall notify the Department in writing, within ten business days of the change(s).

(D) Vessels.

(1) All vessels engaged in the commercial sale of fish and/or fishery products are subject to and shall meet all relevant requirements established in 105 CMR 533.000.

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(2) Holding and Storage.

- (a) All Haddock, Cod, Pollock, Hake, Cusk and Catfish shall be eviscerated when caught and prior to packing. The gills must be removed from April 1st to November 1st.
- (b) The gutting of fish at sea shall be thorough and complete with the removal of all matter from the body cavity.
- (c) Fish shall be thoroughly washed before refrigeration.
- (d) Ice used for refrigeration shall be from an approved source and kept in actual and continuous contact with the fish.

(E) Finfish Operations.

- (1) Tanks used to chill large species of fish (tuna, swordfish, etc.) shall be constructed of materials that meet the requirements for a food-contact surface. The use of canvas or plastic tarps and wood construction is not permitted.
- (2) Filleted fish shall be cooled to a temperature of 45°F (7.2°C) or less within two hours after packing, and stored and shipped under similar temperature conditions.
- (3) Filleting areas shall be equipped with a hand-wash sink supplied with adequate hot and cold running water and a three-bay compartment sink for ware washing.
- (4) The use of any mechanical pumps to move water shall be constructed of food grade materials.
- (5) All receptacles for waste or gurry shall be watertight and covered and shall be thoroughly cleaned after each emptying.
- (6) Only clean refined food-grade salt or filtered brine of a temperature not exceeding 50°F (10.0°C) shall be used in the brining of fish.
- (7) Only salt, sugar, wood smoke, vinegar, pure spices, spice flavoring, sodium benzoate, or other additives Generally Regarded As Safe (GRAS) may be used as fish preservatives. The quantity of sodium benzoate shall not exceed one-tenth of one percent by weight of product and must be designated on the label.
- (8) All processing activities, including but not limited to, storing, thawing, filleting, and packing shall be performed within the physical confines of the facility.

(F) Meat Picking Operations.

- (1) Picking Area. In facilities where the meat is removed from the animal, e.g. lobsters, crabs, whelks, urchins, etc., the room used for the picking shall be separated from other rooms or space in the building by a suitable full partition or walls. Doors to such rooms must be equipped with self-closing devices.
- (2) The picking area shall be equipped with a hand-wash sink supplied with adequate hot and cold running water and a three-bay compartment sink for ware washing.
- (3) Dead Lobsters. The use of dead lobsters, or parts thereof, for processing for human consumption is prohibited.
- (4) Meat not immediately removed from the shell after cooking shall not be sold for human consumption unless it has been kept in a sanitary container and refrigerated at 45°F (7.2°C) or less.
- (5) Meats shall be cooled to a temperature of 45°F (7.2°C) or less within two hours after picking.

(G) Frozen Shell-on Lobster Tails.

- (1) A wholesale seafood operation must be approved in writing and endorsed by the Department and the Division of Marine Fisheries, respectively, prior to conducting a frozen, shell-on lobster tail activity.
- (2) The use of dead lobsters for this activity is strictly prohibited.
- (3) The wholesale seafood operation shall only use live lobsters slaughtered specifically for this activity.
- (4) Following separation of tails for freezing, the remaining portions of each lobster shall be processed by cooking within 30 minutes, or they must be discarded.

(H) Reduced Oxygen Packaging (ROP). Only refrigerated seafood that has one or more of the following safety barriers may be packaged in a reduced oxygen atmosphere:

- (1) water activity (Aw) below .91;
- (2) acidity (pH) of less than 4.6;

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- (3) high levels of non-pathogenic competing organisms that prohibit the growth of pathogenic bacteria;
- (4) held at $\leq 38^{\circ}\text{F}$.
- (5) frozen seafood provided the product is maintained in a frozen state before and after packaging. Product must be kept at 0°F except during processing, where for a maximum of two hours the product may exceed 0°F but shall not exceed 10°F .

(1) Shellfish.

- (1) All wholesale dealers permitted for shellfish activities are subject to the requirements of 105 CMR 533.000 and the NSSP's Model Ordinance. Only those wholesale dealers who voluntarily request and meet the standards for inclusion on the Interstate Certified Shellfish Shippers List (ICSSL) shall be allowed to ship shellfish product interstate.
- (2) Wholesale dealers who are removed, either voluntarily or involuntarily, from the ICSSL shall notify their customers and the Division, that they are no longer involved in the interstate shipment of shellfish.

(3) Shellfish Transactions.

- (a) A harvester may only sell shellfish to a Massachusetts wholesale dealer holding a permit endorsed for shellfish issued by the Division of Marine Fisheries and the Division of Food and Drugs. The direct sale of shellfish by a harvester to a person holding only a wholesale truck permit, restaurant, retail store or consumer is prohibited.
- (b) The direct sale of shellfish to a consumer from a vehicle is prohibited.
- (c) Each transaction between a harvester and a wholesale dealer shall be recorded on a serialized transaction slip approved by the Division. Information recorded on the transaction slip shall include the wholesale dealer's name and permit number, the type and amount of shellfish purchased, date of purchase, and the area from which the shellfish were harvested. Also, the transaction slip documenting the purchase of shellfish shall be imprinted by the wholesale dealer to show the embossed number from the harvester's Shellfish Transaction Card issued by the Division of Marine Fisheries.
- (d) The wholesale dealer, master digger, and harvester shall retain their copy of the transaction slip for at least 90 days.
- (e) A wholesale dealer shall purchase shellfish only from another wholesale dealer or from a harvester or master digger who presents a Shellfish Transaction Card and who is either known to the wholesale dealer or who presents proper photo identification.
- (f) A harvester shall sell shellfish only to a wholesale dealer. This transaction shall only be conducted by:
 - 1. the harvester transporting the product directly to the wholesale dealer's physical facility for sale, or
 - 2. the harvester selling the product to an employee of a wholesale dealer at the landing site, provided that the employee transports the product to the wholesale dealer's facility. Shellfish purchased at the landing site must be transported to the wholesale dealer's facility for washing, grading and tagging prior to entering the marketplace.
- (g) It is prohibited to remove shellfish from the landing area without an approved harvester tag attached to the container as described in the Model Ordinance. Containers with improper tags or no tags are mislabeled and subject to embargo.
- (h) Wholesale dealers shall retain harvester tags for a minimum of 90 days. Tags shall be maintained in an orderly manner, e.g. chronologically, by harvester/dealer, or some other appropriate manner, which facilitates the tracking of dealer purchases.
- (i) Any commingling of shellfish shall be conducted in conformance with Department guidelines.

(4) Bait Operations.

- (a) The shucking and storage of shellfish for use as bait shall be conducted in areas separate from the shucking and storage of food intended for human consumption. There shall be sufficient physical separation in-place to protect food intended for human consumption from contamination by shellfish intended for bait.

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- (b) Containers of bait product must be plainly marked "BAIT" in red lettering no less than two inches in height. The word "BAIT" must appear on a minimum of two sides and the top of the container
- (c) Shellstock intended for bait shall not enter a facility, including loading dock areas, without the container having clear markings indicating the product's intended use.
- (5) Clam Juice.
 - (a) Clam juice intended for human consumption shall not be sold or offered for sale without first being pasteurized in a manner and with equipment approved by the Department.
 - (b) A proper timer and thermometer shall be used to insure that proper time and temperature is achieved. Records of timer and thermometer calibration shall be maintained for one year.
- (6) Scallops.
 - (a) Scallops landed in-the-shell with their viscera and/or roe, and intended for human consumption are subject to the requirements of the Model Ordinance and 105 CMR 533.000.
 - (b) The shucking of scallops landed in the shell must be performed by a wholesale dealer endorsed for this processing activity.
 - (c) Shucked scallop meats treated with any moisture preservative, e.g., sodium tripolyphosphate, shall comply with the moisture content standards established by the U.S. Food and Drug Administration.
- (7) Wet Storage.
 - (a) Wet storage activities shall be conducted in accordance with the Model Ordinance and Department guidelines; and
 - (b) Wholesale seafood operations shall receive written approval from the Department prior to conducting a wet storage activity.
- (8) Shucked Shellfish.
 - (a) Packing operations shall be conducted in a separate room separated from other rooms in the facility by suitable full partitions or walls.
 - (b) Doors to the packing room shall be equipped with self-closing doors and shall be tight-fitting.
 - (c) A shucked shellfish delivery window shall be installed in the partition or wall to the packing room and be equipped with a corrosion-resistant shelf that tilts away from the packing room.
 - (d) The packing room shall be equipped with a hand-wash sink and adequate hot and cold running water and a three-bay compartment sink for ware washing.
 - (e) The packing room shall be large enough to permit the thorough cleaning of all equipment.
 - (f) Retail food establishments shall not remove shellfish meats from the shell. Meals or product on the half-shell may be prepared and served.
- (J) Labeling. All packaged seafood products shall be labeled in accordance with all relevant state and/or federal labeling requirements.

533.008: Market Standard for Shellfish Sold in Massachusetts

- (A) Market Standard. Any shellfish, fresh or frozen, shall be deemed to meet the market standard for shellfish sold in Massachusetts if:
 - (1) It was harvested from an approved area; or
 - (2) It was harvested from a restricted area and was subjected to a process of controlled purification approved by the Department; and
 - (3) Approved analytical methods indicate that it meets the NSSP standards for fecal and pathogenic contamination.
- (B) Procedure when Shellfish Do Not Comply with Market Standard.
 - (1) When the Department is aware of analytical results that indicate that a sample of shellfish is not in compliance with the market standard specified in 105 CMR 533.008(A), the Division shall resample or cause to be re-sampled, shellfish from the same source in order to verify the test result and attempt to ascertain the cause of the problem.

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- (2) If upon resampling and retesting, the shellfish again do not comply with said market standard, the Division may undertake one or more of the following:
 - (a) issue a warning notice to the person or persons responsible for harvesting, handling, processing, or transporting the shellfish and/or notify the responsible permitting authority;
 - (b) seize or embargo all shellfish from the same lot as those that have been found not to comply with the market standard;
 - (c) notify the person or persons responsible for harvesting, handling, processing or transporting the shellfish that all future lots of shellfish from said person or persons will be subject to embargo.
 - (3) The embargo against all shipments specified in 105 CMR 533.008(B)(2)(b) and (c), shall remain in effect until:
 - (a) test results obtained from sampling by the Division from two consecutive lots of shellfish, harvested on different days indicate compliance with the market standard; or
 - (b) test results obtained from sampling by the responsible out of state shellfish control agency from two consecutive lots of shellfish, harvested on different days, under time and temperature conditions which duplicate transportation and delivery to Massachusetts, indicate compliance with the market standard.
 - (c) In either case specified in 105 CMR 533.008(B)(3)(a) or (b), if the shellfish are to be shipped to Massachusetts from out of state, the out of state shellfish control agency shall certify in writing to the Division that the sources of contamination or handling problems causing the failure of the shellfish to comply with the market standard have been identified and corrected.
- (C) Prohibition on Sale of Shellfish in Massachusetts.
- (1) When the Commissioner of Public Health, upon the recommendation of the Director, finds with respect to shellfish from a particular state or country, which serves as a source of shellfish, sold in Massachusetts that:
 - (a) there is evidence of substantial and continuing noncompliance with the shellfish market standard, or
 - (b) multiple notices of embargoes for individual persons have been issued pursuant to 105 CMR 533.008(B)(2), or
 - (c) epidemiological evidence indicates that illnesses traceable to shellfish from multiple sources within a particular state have occurred, or
 - (d) there is other evidence that shellfish from that state may pose a danger to public health and that other regulatory initiatives have failed to control the problem, the Commissioner may notify the appropriate state shellfish control agency that all shellfish originating from or handled in that state or country shall be prohibited from being sold in Massachusetts.
 - (2) Prohibitions on the sale of shellfish under 105 CMR 533.008(C) shall continue until the appropriate source-state or country shellfish control agency satisfactorily certifies to the Division that the shellfish distributed in Massachusetts will meet the market standard in 105 CMR 533.008(A). Copies of current bacteriological test results and inspection reports for each person shall be submitted to the Division in conjunction with such certification.
 - (3) Until such time as the certification has been reviewed and accepted by the Commissioner upon the recommendation of the Division, no shellfish originating from any person in a state notified pursuant to 105 CMR 533.008(B)(2), shall be sold in Massachusetts.

533.010: General Administration

- (A) Enforcement Policy. The following provisions shall cover the administration and enforcement of 105 CMR 533.000.
- (B) The purpose of the enforcement program is to promote the protection of the public health by:
 - (1) ensuring compliance with regulations and conditions of granting the permit;
 - (2) obtaining prompt correction of violations and adverse quality conditions, which may affect public health;
 - (3) deterring future violations and occurrences of conditions adverse to public health; and

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(4) encouraging good manufacturing practices for individual permit holders, and by example, that of the industry, including prompt identification and reporting of potential health or sanitation problems.

(C) The Department will, when circumstances require, publish interpretations of 105 CMR 533.000 and guidelines as necessary to promote uniform application of 105 CMR 533.000, and may make them available to those persons holding a permit under 105 CMR 533.000. The Department will advise permit holders, boards of health, or other interested parties on particular questions regarding the interpretation of 105 CMR 533.000.

533.011: Obtaining a Permit

(A) No person shall operate a wholesale or retail seafood operation without a valid permit granted by the Department and the Division of Marine Fisheries, or in violation of any applicable laws.

(B) Any wholesale seafood operation that substantially alters the natural characteristics of a raw seafood product shall be subject to licensure at 105 CMR 500.000 as a food processing operation, in addition to a permit under 105 CMR 533.000.

(C) Any person seeking to operate a wholesale or retail seafood operation within Massachusetts shall submit an application for a permit to the Division of Marine Fisheries.

(1) Such application shall be on a form provided by the Division of Marine Fisheries.

(2) No permit shall be issued prior to an inspection by and written approval from the Department.

(3) A copy of an approved inspection report by the Department must be submitted by the applicant to the Division of Marine Fisheries prior to the issuance of a permit.

(D) A permit shall be valid only for the activities inspected and approved by the Department and only for the specific location indicated on the permit.

(E) A permit shall remain in effect for the period specified by statute.

(F) A permit may be renewed by applying at least 30 days prior to the expiration of the permit. Application for renewal shall be made in writing on a form provided by the Division of Marine Fisheries.

(G) No holder of a permit shall transfer or assign a permit in any manner, voluntarily or involuntarily, directly or indirectly, or by transfer of control of any company. No holder of a permit shall operate pursuant to a permit transferred or assigned by a prior holder of a permit. No holder of a permit shall transfer an operation to a new location without obtaining a new permit.

(H) Notification to the Department.

(1) Each applicant and holder of a permit shall provide the Department with its complete and correct mailing address. Each applicant and holder of a permit shall notify the Department within seven calendar days of the change of its mailing address. The last address provided to the Department shall be deemed the appropriate address for the service of all orders and notices from the Department.

(2) A holder of a permit shall notify the Department and the Division of Marine Fisheries immediately upon change in ownership or plant location and shall immediately relinquish the permit to the Division of Marine Fisheries upon transfer of ownership or change of location. A holder of a permit shall notify the Department and the Division of Marine Fisheries at least 30 days prior to any change of the name of the plant. The new owner in a change of ownership or the holder of a permit, in the case of a new location, shall submit to the Division of Marine Fisheries an application for a new permit, and shall not operate until said permit is issued. A change in name only shall require the holder of a permit to submit to the Division of Marine Fisheries an application for an amended permit, together with written documentation reflecting the change in name.

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(3) A holder of a permit shall notify the Department in advance of any intention to change endorsed activities. Upon notification, the Department shall inspect the plant to verify compliance with 105 CMR 533.000. No activity may be commenced until the plant is inspected and approved by the Department and endorsed by the Division of Marine Fisheries for said activity.

(4) A holder of a permit shall promptly notify the Department any time that a plant is being remodeled. Upon notification, the Department may inspect the plant to verify compliance with 105 CMR 533.000.

(5) A holder of a permit shall notify the Department immediately when an imminent danger to the public health is present in the plant.

(I) Activities Subject to Permitting. The following operations, and their approved activities, require a permit issued jointly by the Division of Food and Drugs and the Division of Marine Fisheries:

(1) Retail Dealer:

(a) allows the sale of raw fish, whether frozen or unfrozen, shellfish and lobsters at one fixed retail location;

(b) allows the purchase of shellfish from an appropriately permitted wholesale dealer or wholesale truck, or from a certified out-of-state dealer;

(c) allows the purchase of seafood, excluding shellfish, directly from a commercial fisherman;

(d) prohibits the processing, shucking, wet-storing, re-labeling, and repacking of seafood;

(e) proper shellfish tags must be attached to each container and tags must be kept for 90 days; and

(f) requires an inspection and approval from the Department for initial permitting.

(2) Wholesale Truck:

(a) allows the holder to acquire, handle, distribute, ship or sell from the permitted truck raw seafood, whether frozen or unfrozen, in bulk or for resale only;

(b) allows the purchase of finfish, crustaceans and other non-molluscan shellfish seafood products directly from a commercial fisherman;

(c) prohibits the holder from processing, re-labeling or repacking seafood;

(d) prohibits the holder from purchasing shellfish directly from anyone other than a wholesale dealer; and

(e) every wholesale truck requires a separate inspection and approval from the Department.

(3) Wholesale Dealer:

(a) allows the holder to acquire, handle, store, distribute, process, fillet, ship or sell raw seafood products, whether frozen or unfrozen, in bulk or for resale from a single, fixed location;

(b) allows the purchasing of seafood product from a harvester or commercial fisherman;

(c) allows retail sales from a single, fixed location; and

(d) requires an inspection and approval for the specific activities from the Department.

The wholesale dealer is prohibited from engaging in any activity not specifically inspected for and approved by the Department, and endorsed on the permit.

533.012: Seafood Operation Operating Without a Permit

(A) The Department may inspect any facility or vehicle for which it has a reasonable belief contains a seafood operation.

(B) The Department may issue a cease and desist order to any person engaged in a seafood operation without a permit or to any person holding a permit who is conducting an activity not approved by the Department and not endorsed on the permit.

(C) The Department may deny an application for a permit where the applicant was previously operating a facility without a permit or conducting an activity without approval/endorsement.

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(D) The Department may take such other steps as required to bring a facility operating without a permit into compliance or to terminate the operation of the facility, in order to protect the health and safety of the public.

533.013: Inspections

(A) To carry out properly its responsibilities under 105 CMR 533.000 and applicable statutes and to properly protect the health and well-being of the people of the Commonwealth, the Department, or an authorized agent or representative of the Department, is authorized, as often as is deemed necessary for the enforcement of 105 CMR 533.000, to enter, examine, or survey any facility, vehicle or vessel engaged in a seafood operation. Upon reasonable belief that a person is engaged in a seafood operation without a permit, the Department is authorized to inspect the facility.

(B) Inspections may be random, systematic or in response to a specific complaint. An inspection initiated from a specific complaint is not limited to that complaint. At the time of the inspection, the inspector may record all violations.

(C) Agents of the Department, after identifying themselves to the person in charge, may enter all areas of any facility described in 105 CMR 533.013(A), at any reasonable time, for the purpose of making an inspection to ascertain whether the facility is in compliance with 105 CMR 533.000. Any reasonable time includes unannounced inspections, which do not require prior notification of the facility. Individuals engaged in seafood operations shall provide access to Department inspectors at any reasonable time for inspection of the premises.

(D) Agents of the Department may examine all records of the facility to determine which are subject to enforcement under 105 CMR 533.000 and all relevant statutes. Agents may copy all records that are relevant.

(E) The holder of a permit, applicant, or the person in charge at the time of the inspection shall furnish the agent of the Department with all requested records and shall provide the agent with access to all areas of the facility, including but not limited to vehicles, vessels, loading docks, storage and processing areas.

(F) If the holder of a permit, applicant, or person in charge at the time of the inspection refuses entry to an agent of the Department, refuses to permit an authorized inspection, or interferes with the Department, or any agent thereof, in the performance of its duties, the Department may:

- (1) seek in a court of competent jurisdiction an administrative search warrant to search the premises. The warrant application shall apprise the applicant, holder of a permit, or owner of the facility concerning the nature of the inspection and justification for it and the Department may seek the assistance of police authorities in presenting the warrant; and/or,
- (2) take steps to refuse to issue or renew, suspend or revoke the permit in accordance with M.G.L. c.130, § 80 or the ICSSL certification in accordance with the Model Ordinance.

533.014: Notice of Violations/Order to Correct

(A) The Department's inspection report shall constitute the Notice of Violations and the Order to Correct all violations or deficiencies so indicated.

(B) Whenever the Department finds upon inspection, investigation of a complaint or through information in its possession that an applicant or holder of a permit is not in compliance with the provisions of 105 CMR 533.000, the Department shall notify the applicant or holder of a permit of each violation or deficiency. The notice shall include a statement of the violations or deficiencies found; the provision of the law relied upon; the level of severity of the violation or deficiency, when appropriate; a reasonable period of time for correction; and notice that a violation or deficiency may result in a refusal to issue or renew or a suspension or revocation of a permit, a modification or limitation of a permit, and/or a cease and desist order.

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(C) The reasonable period of time for correction shall be within the discretion of the Department to establish in each instance, and shall be based on an evaluation of the type and the severity of each violation or deficiency and shall be noted on the inspection report.

(D) The applicant or holder of a permit shall be responsible for the correction of all violations or deficiencies or the compliance with any order issued pursuant to 105 CMR 533.000 and applicable statutes.

(E) Service of the Notice of Violations/Order to Correct.

(1) Service shall be in person to the applicant or holder of a permit or the person in charge at the time of the inspection, or by certified mail, return receipt requested at the address indicated on the application or permit, or any subsequent address provided to the Department by the applicant or holder of a permit;

(2) If served personally, notice is deemed to be issued on the date when the report is delivered personally;

(3) If served by certified mail, return receipt requested, notice is deemed to be issued on the second business day after it is mailed.

533.015: Plan of Correction

(A) The applicant or holder of a permit, within ten calendar days of issuance of the Notice of Violations/Order to Correct, shall:

(1) correct all violations or deficiencies and file a certification of correction with the Department; and/or

(2) for those items not certified as corrected, file a written plan of correction with the Department.

(B) Each plan of correction and each certification shall:

(1) state the name of the applicant or holder of a permit and the name of the individual and address for receipt of notices;

(2) reference each violation or deficiency cited and for each indicate:

(a) the specific corrective action taken and the date the work was completed; and/or

(b) where, corrective action was not yet completed, the specific corrective action planned and the time table and date for completion, which is in accordance with the date indicated in the Notice of Violations/Order to Correct; and

(3) include the date and the signature of the applicant or holder of a permit or official designee, sworn to under the pains and penalties of perjury.

(C) If the applicant or holder of a permit cannot complete the corrective action within the time frame designated in the Notice of Violations/Order to Correct, the applicant or holder of a permit must petition the Department in writing for an extension of the time to correct. Any petition to extend the time to correct must be submitted to the Department prior to the date indicated in the Notice of Violations/Order to Correct for the violation or deficiency to be corrected. An untimely petition for extension will not be considered unless good cause can be established for the failure to timely file. A petition for an extension of time shall include the reason(s) that the correction cannot be timely completed (e.g. the work requires a permit which will not be issued within the time period granted), including documentary evidence in support and a specific time by which the facility will complete corrections. The Department shall notify the applicant or holder of a permit whether an extension of the time is granted and the duration of the extension, if it is granted.

(D) The Department may re-inspect a facility to determine whether the corrections have been completed.

(E) If upon review of the plan of correction and/or upon reinspection the Department finds that an applicant or holder of a permit remains noncompliant with applicable laws and regulations, the Department may initiate enforcement procedures as set forth in 105 CMR 533.017, or it may request that the applicant or holder of a permit amend and resubmit the plan of correction within ten calendar days of the issuance of the notice or such other time as the Department may specify for resubmission. Nothing herein shall prohibit the Department from initiating an action sooner, if the conditions warrant it.

533.016: Procedures when Infection is Suspected

- (A) In accordance with 21 CFR 110.10, it is the responsibility of the permit holder to protect the integrity of seafood products by:
- (1) developing and implementing a plan for employee health and hygiene (as part of the SSOP developed pursuant to 105 CMR 533.007(A)(2)) that ensures that all personnel report to their supervisors illnesses or health conditions through which there is a reasonable possibility of products, product-contact surfaces or packaging materials becoming contaminated; and
 - (2) taking appropriate protective steps.
- (B) The board of health, where applicable, shall immediately notify the Division of Food and Drugs of suspected disease transmission, and shall keep the Division informed until any investigation is completed.
- (C) The Commissioner or his designee, on his own initiative, or at the request of a local board of health, may require any employee whose duties actually involve the handling of food products, or product-contact surfaces to submit to a medical examination. The examination may include the taking of samples of body fluids, secretions or excretions, whenever said Commissioner or his designee has reason to believe that such examination is necessary for the protection of the public health. The examination shall be without charge to the person examined and at the expense of the Department or of the board of health requesting it.
- (D) In addition, the Department or the board of health, where applicable, may issue an order instituting one or more of the following control measures:
- (1) restriction of particular employee's services to specific areas and tasks in the facility that present no of transmitting the disease;
 - (2) excluding particular employees from the facility; or
 - (3) closing the facility by summarily suspending the permit in accordance with 105 CMR 533.017.
- (E) When the permit holder, person in charge, or manager of a facility knows or has reasonable cause to believe that an employee has contracted a disease transmissible through food or has become a carrier of such a disease, he or she shall immediately notify the Director of the Food Protection Program in the Division and the board of health.
- (F) Any employee who fails to cooperate with any medical or laboratory examination ordered by the Commissioner of Public Health or his or her designee or the local board of health, where applicable, shall immediately be excluded from the performance of duties involving the handling of food or food products, or product-contact surfaces.
- (G) The following diseases are known to be transmissible through food or food products:
- (1) *Salmonella typhi*;
 - (2) *Shigella* spp;
 - (3) *Escherichia coli* 0157:H7 and other *Enterohemorrhagic E. coli* (EHEC);
 - (4) Hepatitis A virus;
 - (5) *Entamoeba histolytica*;
 - (6) *Campylobacter* spp;
 - (7) *Vibrio* spp;
 - (8) *Cryptosporidium* spp;
 - (9) *Giardia* spp;
 - (10) Hemolytic Uremic Syndrome;
 - (11) *Salmonella* spp (non-typhi);
 - (12) *Yersinia enterocolitica*;
 - (13) *Cyclospora cayatanensis*;
 - (14) Any other disease so designated by the Division of Communicable Diseases of the Department in 105 CMR 300.000: *Reportable Diseases and Isolation and Quarantine Requirements*.

533.017: Enforcement

- (A) Immediate Suspension of a Permit without a Prior Hearing.
- (1) The Department may, without a prior hearing, suspend a permit or other approval upon making a finding that there exists an imminent danger to the public health.

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(2) Procedures for the Immediate Suspension of a Permit.

(a) an immediate suspension order shall be in writing and shall be provided to the holder of a permit or to the person in charge of the facility or vehicle and a copy may be posted at the facility. The order shall state:

1. the reason(s) for the suspension;
2. the violation(s) leading to the determination that the facility or vehicle is operating in a manner, which is a danger to the public and the applicable provision(s) of law;
3. that all operations or one or more operations of the facility or vehicle shall immediately cease and desist; and
4. that a prompt hearing shall be afforded pursuant to the procedures established in 105 CMR 533.017(H).

(b) the order immediately suspending the permit shall be served in accordance with 105 CMR 533.017(G). The order shall be effective upon in-hand delivery of the order to the facility or vehicle or two days after mailing of the order by certified mail. If there is in-hand service, and the person whose name appears on the permit is not present at the time of such delivery, or if the holder of a permit is a corporation or other firm, a copy of the order of suspension shall also be mailed by certified mail.

(c) the Department may end the immediate suspension at any time if reasons for the suspension no longer exist.

(B) Immediate Actions Against an ICSSL Certification, without a Prior Hearing.

(1) The Department may, without a prior hearing, suspend the ICSSL certification of a certified dealer for any violation or series of violations of the standards established in the Model Ordinance, including but not limited to:

- (a) a deficiency or activity that presents an imminent danger to the public health;
- (b) failure to immediately correct a critical deficiency;
- (c) failure to timely submit an approved correction plan;
- (d) failure to timely comply with an approved correction plan for a key or critical deficiency;
- (e) citation for improper tagging; or
- (f) citation for operation without a proper endorsement.

(2) Refusal to Issue or Renew an ICSSL Certification.

(a) The Department may refuse to issue an ICSSL certification if the applicant fails to meet the standards for initial certification established in the Model Ordinance, including but not limited to:

1. no critical deficiencies;
2. not more than two key deficiencies;
3. not more than three other deficiencies; and
4. the initial certification shall include a compliance schedule to correct the deficiencies if necessary.

(b) The Department may refuse to renew an ICSSL certification if the applicant fails to comply with the standards for certification renewal established in the Model Ordinance, including but not limited to:

1. eliminate any critical deficiencies;
2. agree to a compliance schedule which carries forward into the next certification period no more than one key and two other deficiencies identified in previous inspection;
3. address any new key or other deficiencies in a new or revised compliance schedule; and
4. meet the requirement of certification described in 105 CMR 533.017(B)(2)(a).

(c) The Department may refuse to issue or renew an ICSSL certification if the applicant fails to timely submit an approved correction plan.

(3) Procedures for Suspending or Refusing to Issue or Renew a Dealer's ICSSL Certification.

(a) A suspension or a refusal to issue or renew the ICSSL Certification order shall be in writing and shall be immediately provided to the holder of the ICSSL certification or to the person in charge of the facility and a copy may be posted at the facility. The order shall state:

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1. the reason(s) for the suspension or refusal to issue or renew the certification;
2. the violation(s) leading to the suspension or refusal to issue or renew the certification and the applicable provision(s) of law;
3. that all operations or one or more operations of the facility shall immediately cease and desist; and
4. that a hearing before the Director of the Division of Food and Drugs/Food Protection Program or his designee, if requested, shall be afforded within three business days.

(b) The order immediately suspending or refusing to issue or renew the certification shall be served in accordance with 105 CMR 533.017(G). The order shall be effective upon in-hand delivery of the order to the facility or two days after mailing of the order by certified mail. If there is in-hand service, and the person whose name appears on the certification is not present at the time of such delivery, or if the holder of the certification is a corporation or other firm, a copy of the order of suspension or refusal to renew shall also be mailed by certified mail.

(c) The Department may end the suspension of the certification at any time if reasons for the suspension no longer exist. The Department shall notify the federal program to include the facility's name in the next available publication.

(d) Following the refusal to renew the certification, a dealer must meet the requirements of initial certification prior to restoration to the ICSSL.

(C) Refusal to Issue a Permit or Approval.

(1) The Department may refuse to issue a permit or approval based on any one or more of the following grounds. Each of the grounds shall constitute full and adequate grounds to refuse to issue a permit or approval:

- (a) failure to submit a permit application in accordance with the proper procedures;
- (b) failure to submit the required permit fee;
- (c) failure to comply with any provisions of 105 CMR 533.000;
- (d) denial of entry to agents of the Department or any attempt to impede the work of a duly authorized agent or representative of the Department;
- (e) keeping or providing false or misleading statements or documents to the Department;
- (f) the applicant operated the facility or vehicle or any facility or vehicle without a permit or approval, or upon the expiration of a permit or approval;
- (g) the applicant or, if the applicant is a corporation, a corporate officer or the owner of the facility or vehicle, has been convicted of, pled guilty or nolo contendere to, or has, in a judicial proceeding, admitted facts sufficient to find that s/he is guilty of a crime relating to the processing, storage, distribution or sale of seafood in connection with the business;
- (h) the applicant or, if the applicant is a corporation, a corporate officer or the owner of the facility or vehicle has engaged in conduct that endangers the public health;
- (i) a facility or vehicle owned or operated by the applicant which is, or was, the subject of a proceeding(s) and which proceeding is still ongoing or resulted in the suspension, denial, or revocation of a permit or approval or refusal to renew the permit or approval;
- (j) failure to pay any federal, state or local taxes as required by law; pursuant to M.G.L. c. 62C, § 49A; or
- (k) failure to comply with local regulations/ordinances related to the physical operation of the facility or vehicle.

(2) Notice of Refusal to Issue a Permit or Approval:

(a) shall be in writing and shall specify the specific reasons(s) for which the permit or approval was denied, the applicable provision of law and the procedure for requesting a hearing set forth in 105 CMR 533.017(H), unless no hearing is required pursuant to M.G.L. c. 30A, § 13; and

(b) shall be served on the applicant in accordance with 105 CMR 533.017(G).

(3) Hearing. to obtain a hearing, the applicant shall follow the procedures set forth in 105 CMR 533.017(H).

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(D) Suspension or Refusal to Renew a Permit or Approval after Opportunity for a Hearing.

(1) Suspension. The Department may suspend a permit or approval to operate a facility or vehicle or one or more particular activities of the facility, if the facility or the operation does not comply with any one or more of the requirements of 105 CMR 533.000.

(a) The suspension of a permit shall continue for a period of time specified by the Department or until the Department determines that the required corrections are made.

(b) The suspension of a permit or specific activity shall automatically result in the suspension of the dealer's ICSSL certification or certification for the specified activity that was suspended.

(c) The Department may suspend those activities related to shellfish when the dealer's ICSSL certification is suspended, revoked, or not renewed.

(2) Refusal to Renew. The Department may refuse to renew a permit or approval if the facility or vehicle does not comply with any one or more of the following grounds. Each of the grounds shall constitute full and adequate grounds to refuse to renew a permit or approval:

(a) any of the grounds specified in 105 CMR 533.017(A)(1);

(b) any of the grounds specified in 105 CMR 533.017(C)(1); or,

(c) any of the grounds specified in 105 CMR 533.017(D)(1) or (E).

(E) Revocation of a Permit, Approval, or ICSSL Certification after Opportunity for a Hearing.

The Department may revoke a permit or approval to operate a facility or vehicle or a particular operation or a dealer's ICSSL certification, if the facility, vehicle or operation does not comply with any one or more of the following grounds. The revocation shall be for a period of one year from the date of the final order unless otherwise indicated. Each of the following grounds shall constitute full and adequate grounds to revoke a permit approval or certification:

(1) repeated or extremely serious violation(s) of any of the requirements of 105 CMR 533.000 including violations of the Model Ordinance;

(2) interference with the Department or any of its authorized agents in the performance of its duties including, but not limited to, refusal to provide access to inspect any part of the premises, harassment, threats, intimidation, abuse or assault;

(3) a criminal conviction of the holder of a permit, approval or certification, or if the holder of a permit, approval or certification is a corporation a criminal conviction of a corporate officer or the owner of the facility or vehicle, for a crime relating to the harvesting, processing, storage, distribution or sale of seafood in connection with the permitted or certified business;

(4) keeping or submitting any misleading or false records or documents required by 105 CMR 533.00 or related law;

(5) failure to pay any federal, state or local taxes as required by law; pursuant to M.G.L. c. 62C, § 49A.

(F) Notice of Intent to Suspend, or Refuse to Renew a Permit or Approval or to Revoke a Permit, Approval or Certification:

(1) shall be in writing and shall specify the specific violation(s) including the condition constituting the violation and the applicable provision of law for which the permit, approval or certification is to be suspended, revoked or not renewed and the procedure for requesting a hearing set forth in 105 CMR 533.017(H).

(2) shall be served on the holder of a permit or other responsible person in accordance with 105 CMR 533.017(G).

(G) Service of Orders and Notices of Intent. Any orders issued pursuant to 105 CMR 533.000 *et seq.*, whether or not they are prior to a hearing or after opportunity for a hearing shall be served as follows:

(1) by certified mail, return receipt requested at the address provided pursuant to 105 CMR 533.011(H)(1); or

(2) in-hand service by an agent of the Department.

(H) Hearings.

(1) the Department shall conduct any hearing requested pursuant to 105 CMR 533.017(B), before the Director of the Division of Food and Drugs, Food Protection Program.

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- (2) The Department shall conduct all other adjudicatory proceedings in accordance with M.G.L. c. 30A and all applicable provisions of the Standard Adjudicatory Rules of Practice and Procedure 801 CMR 1.01 *et seq.*
- (3) Upon written request pursuant to 801 CMR 1.01 *et seq.*, the applicant or holder of a permit or certification shall be afforded an opportunity for a hearing. Written requests for a hearing for any enforcement proceeding under 105 CMR 533.000 must be received by the Department within 14 calendar days of the issuance of the Department's action.
- (4) The failure to timely request a hearing constitutes a waiver of the right to a hearing.
- (5) Any settlement of any enforcement action commenced under 105 CMR 533.000 shall be final and shall not be subject to judicial review.
- (6) A hearing based on an order for an immediate suspension pursuant to 105 CMR 533.017(A), without a prior hearing, shall be conducted promptly after the Department receives the request for a hearing.
- (7) A hearing based on an action with an opportunity for a prior hearing shall be commenced within a reasonable time period after the Department receives the request for a hearing.
- (8) Failure to hold a hearing within the time periods specified herein shall not affect the validity of any order.
- (9) The applicant or holder of a permit, approval or certification shall be provided an opportunity to be heard and to demonstrate why the order should be modified or withdrawn or why the proposed action should not be upheld. Any oral testimony provided at a hearing shall be recorded verbatim.
- (10) In the case of an immediate suspension of a permit or approval pursuant to 105 CMR 533.017(A), the hearing officer shall determine whether the Department proved by a preponderance of evidence that there existed, immediately prior to or at the time of the suspension, an imminent danger to the public health.
- (11) In the case of all actions taken against any ICSSL certification as well as any refusal to issue a permit or approval or any notice of intent to suspend, revoke, or refuse to renew a permit or approval, the hearing officer shall determine whether the Department proved by a preponderance of the evidence that the permit, approval or certification should be denied, suspended, revoked or not renewed, based on the relevant facts as they existed at or prior to the time the Department initiated the action.
- (12) The Notice of Violations/Order to Correct shall constitute *prima facie* evidence of the conditions listed therein.
- (13) If the hearing officer finds any single ground for summary suspension, refusal to issue, suspension, revocation, or refusal to renew a permit, approval or certification, the hearing officer shall render a recommended decision affirming the decision of the Department.

(I) Public Health Council and Judicial Review.

- (1) The decision of the Director of the Food Protection Program pursuant to 105 CMR 533.017(H)(1) is a final agency decision and is subject to judicial review.
- (2) The recommended decision of the hearing officer in any adjudicatory proceeding conducted pursuant to 105 CMR 533.017(H)(2) shall be reviewed by the Commissioner and the Public Health Council. After review, their decision shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.
- (3) Any applicant, holder of a permit, approval or certification, or other responsible person that fails to exercise the right to an adjudicatory proceeding or withdraws the request for a hearing, pursuant to 105 CMR 533.017(H)(2), waives the right to administrative review by the Public Health Council. In such cases, the Commissioner shall issue the final agency decision.
- (4) The failure to request an adjudicatory proceeding or the withdrawal of a request for an adjudicatory hearing shall be deemed a failure to exhaust administrative remedies.

(J) Criminal Penalties. Pursuant to the applicable provisions of M.G.L. c. 94, §§ 88D and 305A, and M.G.L. c. 130, §§ 80 and 81 criminal penalties may be imposed.

(K) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 533.000 is mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

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533.020: Severability

The provisions of 105 CMR 533.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be affected.

533.030: Variance

(A) The Department may in its discretion, vary the application of any provision of 105 CMR 533.000 with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice; provided, that the decision of the Department shall not conflict with the spirit of 105 CMR 533.000; and

(B) All requests for a variance shall be in writing and submitted to the Director of the Food Protection Program.

(C) A copy of any such variance shall be available to the public.

REGULATORY AUTHORITY

105 CMR 533.000: M.G.L. c. 94, §§ 88C, 192, 305A; M.G.L. c. 111, §§ 3 and 5; M.G.L. c. 130, § 80.

NON-TEXT PAGE